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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,391	11/14/2000	Jurgen Bongs	02481.1716	3417

22852 7590 06/18/2002

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MARX, IRENE

ART UNIT	PAPER NUMBER
1651	7

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/700,391	Applicant(s) Bongs et al.
	Examiner Irene Marx	Art Unit 1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Apr 26, 2002
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11-21 is/are pending in the application.
- 4a) Of the above, claim(s) 11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Applicant's election with traverse of Group II, claims 12-21 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that all the claims are so linked to form a single general inventive concept as required by PCT rules.

However, no common inventive concept is shared among groups I and II since the processes of groups I and II lacks a "special technical features" as defined in Rule 13.2, meaning a technical feature that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. Applicant asserts that the use of a polymer support system to support the reaction is the linking element. Yet the polymer support system as claimed is not inventive as adequately demonstrated by Lorenzen *et al.* or Eckstein *et al.* (See, e.g., Abstracts). Therefore, the method of catalysis lacks those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claim 11 is withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is vague, indefinite and confusing in the recitation of "insulins and their analogs". It is unclear what is intended to be encompassed by "analog" in this context. Is it analogy by structure or by function? In addition, nature of "corresponding precursors" of these analogs is not set forth. Therefore, the metes and bounds of the claim are unclear.

Claim 14 is incomplete in depending on a non-elected claim.

Claim 19 is confusing and redundant in the recitation "0.5 to .5 U/ml".

Claims 12-21 are incomplete in the absence of a recovery step for the product produced. The nature of the product produced is not clearly delineated.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claims 12 and 13 are vague, indefinite and confusing in the recitation of "substantially no pores". The number of pores intended is not disclosed in the as-filed specification. Therefore, the number of pores intended to be claim designated cannot be discerned with any precision.

Claim 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend on other claims in the alternative. See MPEP § 608.01(n). Accordingly, the claim not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Lorenzen *et al.*

The claims are directed to the enzymatic extraction of biomolecules such as peptides using a polymeric support material which has no pores or substantially no pores.

The reference teaches the enzymatic extraction of the biomolecules phosphopeptides from casein using a polymeric support material which has no pores or substantially no pores, such as oxirane acrylic beads using trypsin (See, e.g., page 119, Materials and Methods.)

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jakubke *et al.* taken with Lorenzen *et al.*, Eckstein, Huwig *et al.* and Hillegas *et al.*.

The claims are directed to the enzymatic extraction of insulin using a polymeric support material which has no pores or substantially no pores.

Jakubke *et al.* teach extraction of insulin using trypsin immobilized in a carrier which appears to be substantially non-porous (See, e.g., Examples).

However, even if the carrier is substantially porous, the use of non-porous carriers in the enzymatic production and extraction of biomolecules is old and well known in the art, as adequately demonstrated by Lorenzen *et al.* teaches the enzymatic extraction of the biomolecules phosphopeptides from casein using a polymeric support material which has no pores or substantially no pores, such as oxirane acrylic beads using trypsin (See, e.g., page 119, Materials and Methods.). In addition, Eckstein teaches the use of an Eupergit^R carrier in a similar process of immobilizing trypsin, while Huwig *et al.* disclose the use of Eupergit^R C250L for an enzymatic bioconversion. In addition, Hillegas *et al.* tout the advantages of using a non-porous carrier in various applications (See, e.g., col. 5, lines 10-20).

The activity of the trypsin used in the references is not disclosed. However, the adjustment of process conditions for optimization purposes of conditions identified as result-effective variables

cited in the references would have been prima facie obvious to a person having ordinary skill in the art.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in immobilizing trypsin on copolymer carrier of methacrylamide and N,N'-bis-methacrylamide monomers having oxirane groups in order to extract useful biomolecules such as insulin from the enzymatic reaction.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Jakubke *et al.* using immobilized trypsin to extract insulins by substituting a non-porous carrier for trypsin, including methacrylamide and N,N'-bis-methacrylamide monomers having oxirane groups, according to the teachings of Lorenzen *et al.*, Eckstein, Huwig *et al.* and Hillegas *et al.* for the expected benefit of maximizing the yield of this important protein necessary for the treatment of diabetes.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651